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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,095	03/16/2000	WOLF-GEORG FORSSMANN	P65141US0	5210

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EXAMINER
KAM, CHIH MIN

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 01/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/508,095	ZUCHT ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-5* is/are pending in the application.

4a) Of the above claim(s) *3* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1, 4 and 5 as well as a peptide of SEQ ID NO:22 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that nucleic acids of Group II encode the peptides of Group I, thus, the claims of two groups exhibit corresponding special technical features and applicants further assert that Example 17 in "Administrative Instructions Under The PCT, Annex B part 2, Examples Concerning Unity of Invention" indicates the protein and the DNA sequence encoding the protein exhibit corresponding special technical features, thus, unity between the two is accepted. This is not found persuasive because in the instant application, claim 3 of Group II cites using the nucleic acids for treating diseases, which is gene therapy. The use of nucleic acid for treating diseases does not have the same special technical features as using peptide because the two methods have different method steps, use different agents and produce different effects. Accordingly, the groups are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper. Therefore, claims 1, 4, 5 and SEQ ID NO:22 are examined.

Abstract

2. Applicant is reminded of the proper format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

Informalities

The disclosure is objected to because of the following informalities:

3. The specification is objected to for not conforming C.F.R.37 1.822 (d)(1) since the amino acids in the peptide sequences of the invention are listed with one letter abbreviation (page 3) instead of the required three-letter abbreviation with the first letter as an upper case character. Appropriate correction is required.

4. Specification contain amino acid sequences at page 3 and indicates "SEQ ID NO:1-24, respectively in order of appearance" for the listing amino acid sequences, which is not appropriate because R_1-ARRARVVWCAVGE-R_2 is SEQ ID NO:15 and R_3-CIAL-R_4 is SEQ ID NO:16 according to the order of appearance. However, SEQ ID NO:15 is R_3-CIAL-R_4 and SEQ ID NO:16 is R_1-ARRARVVWCAVGE-R_2 in the sequence listing. Each amino acid sequence should have a "SEQ ID NO:" listed separately next to it. Appropriate correction is required.

5. The specification is objected to for "R_1, R_3 independently represent NH_2" and "R_2, R_4 independently represent COOH, $CONH_2$" (page 3) since each amino acid in the peptide (HN-CH(R)-CO) has already contained the amino (NH) and carbonyl (CO) groups. It is incorrect to write "R_1, R_3 independently represent NH_2" and "R_2, R_4 independently represent COOH, $CONH_2$" for N- and C-terminal ends of the peptide, it should be "R_1, R_3 independently represent H" and "R_2, R_4 independently represent OH, NH_2". Appropriate correction is required.

Claim Objections

6. Claim 5 is objected to for not conforming C.F.R.37 1.822 (d)(1) since the amino acids in the peptide sequences of the invention are listed with one letter abbreviation instead of the required three-letter abbreviation with the first letter as an upper case character. Claim 5 is also

objected to for not listing "SEQ ID NO:" for each amino acid sequence (see explanation in paragraph 4).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1, 4 and 5 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is directed to the use of peptides from cow or human milk, the amidated, acetylated, sulfated, phosphorylated, glycosylated, oxidized derivatives or fragments thereof, and the peptides by combination of the peptides from milk with derivatives or fragments by chemical

bonding, which have bifidogenic properties, for the preparation of a medicament in treating diseases caused by various microorganisms. The specification indicates the peptides isolated and purified from cow milk or human milk can promote the growth of desired bacteria such as bifidobacteria more than that of other bacteria or by selectively inhibiting the undesired bacteria, which is defined as "bifidogenic" (page 3, first paragraph), and the peptide can be contained in medicaments or in food, and further asserts the peptides are suitable for treating diseases caused by various microorganisms (pages 4-5). The Examples have only indicated the isolation and purification of certain peptides (Example 1), the method of monitoring the growth-regulating activity on *E. coli* (Example 2), the method of monitoring the growth-regulating activity on *Bifidobacterium bifidum* (Example 3), and a formula to define bifidogenic (Example 4). However, the specification has not demonstrated any peptide has the bifidogenic property as indicated by the formula {(BW/B0)-(EW/E0)≥ 0.15}, no data has been shown for any peptide. There is no *in vitro* or *in vivo* data indicating the peptide is effective in treating any disease state cited in the claim, e.g., the dose-response curve for *in vitro* assay, the effective amount of the peptide, the time and the desired outcome for the treatment. Therefore, it is necessary to have additional guidance on the identity of the peptide derivatives, the measurement of bifidogenic property of the peptide and the effective dose of the peptide for treating a targeted disease and to carry out further experimentation to assess the effect of the peptides with bifidogenic property. Since the claims encompass many peptide derivatives and the treating conditions for each disease state is not described in the specification, the invention is highly unpredictable regarding the outcome of the treatment. The general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide specific guidance on the

identity of the peptide derivatives and the treating conditions for various diseases. Thus, the disclosure is not enabling for the reasons discussed above.

The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breath of the claims, the absence of working examples, the state of the prior art and relative skill of those in the art, the unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1, 4 and 5 provide for the use of peptides obtained from cow milk or human milk, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

10. Claims 1, 4 and 5 are indefinite in that it fails to point out what is included or excluded by the claim language. Is a method of use, or a method of making or peptides being claimed? The claims cross three (3) statutory classes of invention. The entirety of claim 1 appears to be directed to obtain the protein but none to "a method of using" the protein.

11. Claims 1, 4 and 5 are indefinite because of the use of the term "of the amidated, acetylated, sulfated, phosphorylated, glycosylated, oxidized derivatives or fragments thereof". The term "of the amidated, acetylated, sulfated, phosphorylated, glycosylated, oxidized

derivatives or fragments thereof" renders the claim indefinite, it is unclear what amino acid sequence the derivative or fragment has as compared to the parent compound, and which amino acid(s) is(are) being amidated, acetylated, sulfated, phosphorylated, glycosylated and oxidized.

12. Regarding claims 1, 4 and 5, the phrase "such as" or "for example" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

13. Claims 1, 4 and 5 are indefinite because of the use of the term "by the combination of the peptides, fragments or derivatives by chemical bonding". The term "by the combination of the peptides, fragments or derivatives by chemical bonding" renders the claim indefinite, it is unclear what amino acid sequence is obtained as to combining the peptides, fragments or derivatives by chemical bonding. Claims is also indefinite as to "deviations in the oral……, caries", it is not clear how much deviation in the oral, intestinal and vaginal floras, caries would turn to a disease state.

14. Claim 4 is indefinite as to the extraneous period "Nos.". Use "NO:" instead.

15. Claim 5 is indefinite for using the terms "R_1, R_3 independently represent NH_2" and "R_2, R_4 independently represent COOH, $CONH_2$". It is not clear what groups the N- and C-terminal ends of the peptide have since each amino acid (HN-CH(R)-CO) in the peptide has already contained the amino (NH) and carbonyl (CO) groups. Use of "R_1, R_3 independently represent H" and "R_2, R_4 independently represent OH, NH_2" is suggested.

16. Claims 4 and 5 are indefinite because the claim contains recitation of non-elected sequences.

Conclusion

17. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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January 18, 2002

Christopher S. Low

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